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10/578,402	11/21/2006	Laurie H. Glimcher	HUI-045CP2US	3013
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EXAMINER HILL, KEVIN KAI				
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1633				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/578,402

**Applicant(s)**

GLIMCHER ET AL.

**Examiner**

KEVIN K. HILL

**Art Unit**

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 May 2006.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-23 and 46-54 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☒ Claim(s) 1,2,4-23 and 46-54 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

***Election/Restrictions***

**1. Restriction to one of the following inventions is required under 35 U.S.C. 121:**

- I. Claims 2-5 and 11-17, drawn to a method for identifying a compound which modulates an interaction between a first and a second polypeptide, the method comprising contacting *in vitro* a non-transgenic cell having a first polypeptide comprising a binding portion of a KRC polypeptide and a second polypeptide comprising a binding portion of a polypeptide selected from the group consisting of GATA3, SMAD or Runx2, classified in class 435, subclass 4.
- II. Claims 2-17, drawn to a method for identifying a compound which modulates an interaction between a first and a second polypeptide, the method comprising contacting *in vitro* a transgenic cell having a first polypeptide comprising a binding portion of a KRC polypeptide and a second polypeptide comprising a binding portion of a polypeptide selected from the group consisting of GATA3, SMAD or Runx2, classified in class 435, subclass 69.1.
- III. Claims 2-5 and 11-17, drawn to a method for identifying a compound which modulates an interaction between a first and a second polypeptide, the method comprising contacting *in vivo* a non-transgenic cell having a first polypeptide comprising a binding portion of a KRC polypeptide and a second polypeptide comprising a binding portion of a polypeptide selected from the group consisting of GATA3, SMAD or Runx2, classified in class 435, subclass 4.
- IV. Claims 2-7 and 11-17, drawn to a method for identifying a compound which modulates an interaction between a first and a second polypeptide, the method comprising contacting *in vivo* a transgenic cell having a first polypeptide comprising a binding portion of a KRC polypeptide and a second polypeptide comprising a binding portion of a polypeptide selected from the group consisting of GATA3, SMAD or Runx2, classified in class 800, subclass 3.

- V. Claim 19, drawn to a method of identifying compounds which modulate a biological activity of mammalian KRC, the method comprising contacting *in vitro* cells deficient in KRC or a molecule in a signaling pathway involving KRC with a test compound, classified in class 435, subclass 69.1.
- VI. Claims 19-20, drawn to a method of identifying compounds which modulate a biological activity of mammalian KRC, the method comprising contacting *in vivo* cells deficient in KRC or a molecule in a signaling pathway involving KRC with a test compound, classified in class 800, subclass 3.
- VII. Claim 22, drawn to an *in vitro* method of identifying compounds which modulate a biological activity of mammalian KRC, wherein the indicator composition is a non-transgenic cell that expresses KRC and at least one molecule selected from the group consisting of GATA3, SMAD and Runx2, classified in class 435, subclass 4.
- VIII. Claim 22, drawn to an *in vitro* method of identifying compounds which modulate a biological activity of mammalian KRC, wherein the indicator composition is a transgenic cell that expresses KRC and at least one molecule selected from the group consisting of GATA3, SMAD and Runx2, classified in class 435, subclass 69.1.
- IX. Claim 22, drawn to an *in vivo* method of identifying compounds which modulate a biological activity of mammalian KRC, wherein the indicator composition is a non-transgenic cell that expresses KRC and at least one molecule selected from the group consisting of GATA3, SMAD and Runx2, classified in class 435, subclass 4.

- X. Claim 22, drawn to an *in vivo* method of identifying compounds which modulate a biological activity of mammalian KRC, wherein the indicator composition is a transgenic cell that expresses KRC and at least one molecule selected from the group consisting of GATA3, SMAD and Runx2, classified in class 800, subclass 3.
- XI. Claim 23, drawn to an *in vitro*, cell-free method of identifying compounds which modulate a biological activity of mammalian KRC, classified in class 436, subclass 63.
- XII. Claims 47-48, drawn to a transgenic non-human animal in which a KRC transgene is mis-expressed, classified in class 800, subclass 13.
- XIII. Claims 49-54, drawn to a transgenic non-human animal in which the gene encoding KRC is disrupted, classified in class 800, subclass 13.

**Claim 1 links Groups I-IV.**

**Claim 18 links Groups V-VI.**

**Claim 21 links Groups VII-XI.**

**Claim 46 links Groups XII-XIII.**

Inventions I-XI are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different designs, modes of operations and effects, as evidenced by the substitute specification disclosing that the contacting step may be performed *in vitro* or *in vivo* (pg 12, lines 17-20), and the cell may be a transgenic or non-transgenic cell (pg 22, line 24- pg 23, line 11; pg 27, lines 15-17).

Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions XII-XIII are directed to related products. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different designs and effects, wherein those of ordinary skill in the art recognize that knock-out genotypes yield distinctly different phenotypes than aberrant expression genotypes. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions XII-XIII and Inventions I-XI are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the methods may be performed using a plurality of cells and/or organisms comprising distinctly different genotypes.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, Applicant must indicate which of these claims are readable upon the elected invention.

Should Applicant traverse on the ground that the inventions are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Claim 1 links Groups I-IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), Claim 1.

Claim 18 links Groups V-VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), Claim 18.

Claim 21 links Groups VII-XI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), Claim 21.

Claim 46 links Groups XII-XIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), Claim 46.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the



continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP §804.01.

**2. Should Applicant elect any of Inventions I-IV and VII, a species election is required under 35 USC 121.** Claims 1 and 22 are generic to the following disclosed patentably distinct species of host cell types, wherein the specification discloses a plurality of distinctly different cell types (pg 27, line 18; pg 30, line 31-pg 31, line 2). The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed host cell type species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

**3. Should Applicant elect any of Inventions V-XI, a species election is required under 35 USC 121.** Claim 18 is generic to the following disclosed patentably distinct species of KRC or molecules in a signaling pathway involving KRC, wherein the specification discloses a plurality of distinctly different molecules (e.g. pg 27, lines 4-5; pg 8, lines 14-30; pg 9, lines 4-10; pg 11, lines 10-18). The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

**4. Should Applicant elect any of Inventions VI, VII-X, XII-XIII, a species election is required under 35 USC 121.** Claims 20, 22 and 46-47 are generic to the following disclosed patentably distinct species of non-human animals, wherein the specification discloses a plurality

of distinctly different embodiments (pg 23, line 5; pg 27, line 18; pg 31, line 2). The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of non-human animals for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

**5. This application contains claims directed to the following patentably distinct species of determination method steps.** The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of determination method steps from the lists recited in claims 9-11 and 13-15 in accordance with Applicant's elected invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic.

**6. This application contains claims directed to the following patentably distinct species of second polypeptide indicators recited in Claims 1, 4-5 and 22.** The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed second polypeptide indicator species, i.e. GATA3, SMAD2, SMAD3, or Runx2, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1 and 21 are generic.

**7. This application contains claims directed to the following patentably distinct species of biological activities that are to be measured.** The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such

species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed biological activity species that is to be measured from the list recited in Claims 13, 19 and 21, in accordance with Applicant's elected invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1 and 18 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected species.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to KEVIN K. HILL whose telephone number is (571)272-8036. The Examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin K. Hill/

Examiner, Art Unit 1633